

**EPA Response to Syngenta Comments on Environmental Fate & Effects Chapter
of
Atrazine Reregistration Eligibility Document of 12/8/00**

Summary of Syngenta's Comments on pages 1 and 2:

Syngenta notes that the Giddings et al 2000 study considered effects on biomass and primary productivity, as well as effects on species abundance and recovery, community structure (including diversity), and direct and indirect effects on invertebrates, fish, and water quality.

EPA's Response:

The limiting statements found in the Agency's document will be changed and the statements will read as follows:

Giddings, et al., 2000, have reviewed microcosm and mesocosm data and concluded that no lasting ecological damage results from exposure of aquatic communities to atrazine concentrations below 50 ug/L. They suggest that aquatic communities are resilient and will easily recover from atrazine contamination at 50 ug/L. In addition, they maintain that sensitive species would be replaced with less sensitive species with the same ecological function.

EFED comes to a significantly different conclusion after reviewing some of the same data. First, studies such as Kettle et al. 1987 provide quite a bit of evidence to the contrary - namely, that 20 ug/L of atrazine can result in extreme negative impacts on the aquatic communities. By maintaining that sensitive species would be replaced with less sensitive species, Giddings et al. suggest that changes in species assemblages do not result in adverse effects on aquatic communities. Recovery in communities is always uncertain and proof of it requires the collection of considerable species specific data, none of which has been referenced by the authors. Finally, EFED does not believe it is possible to perform a proper assessment of reproductive effects of atrazine on plants without the data from true plant reproductive studies, and again, such data has not been referenced by the authors. EFED also notes that there are inevitably other herbicides present in contaminated water bodies, whose combined effects would act to lower the effective levels at which individual chemicals such as atrazine cause impact. Consequently, EFED does not agree with the level of 50 ug/L as an NOAEC for community-based effects for atrazine.

Summary of Syngenta's Comments on pages 2, 32, and 34:

Syngenta identified certain statements in the EPA document as being misleading or incorrect. Specifically, Syngenta mentioned the statement on page 7 (under Summary of Major Risk Concerns): "*continued atrazine use is likely to pose a risk to health and integrity of some aquatic communities*"; the statement on page 9, 3rd paragraph, line 5; "*These data provide a strong basis for concluding that the continued use of atrazine is likely to result in adverse effects on some aquatic communities.*"; and page 9, paragraph 4, lines 4-6 a "*multiple lines of evidence*" approach was used to derive the final conclusion - high risk of atrazine to aquatic communities.

EPA's Response:

The statements identified by Syngenta as misleading or incorrect are based on a refined ecological risk assessment. While they do not imply any quantification of magnitude or probability of effect, since they are based on extensive additional published ecotoxicological and exposure monitoring data, they do imply a greater likelihood of risk to some aquatic communities than indicated in the preliminary risk assessment using risk quotients. Since the Agency has clearly identified the approach used for its refined assessment, and considering that indirect effects on aquatic communities would be very difficult to characterize in the field after 40 years of extensive atrazine use, the statements are neither misleading nor incorrect.

Syngenta comment page 3 and 17

Syngenta questioned statements in the RED document that "atrazine is associated with endocrine disruption" in wildlife (Environmental Risk Conclusions, pp. 3 and 11 and elsewhere), as well as the cited references supporting the statement: Dodson *et al.* 1999 and Petit *et al.* 1999. In response, Syngenta states that it has "voluntarily undertaken investigations to consider the potential for atrazine to function as an endocrine modulator in wildlife species. They referenced a report by an "independent panel of university scientists" to examine the available literature "relative to endocrine disruption in fish, amphibians and reptiles." [A Risk-Based Assessment of Endocrine System Responses in Fish, Amphibians, and Reptiles to Atrazine; (919)(710-97, 72104)]. They also referenced a report containing partial results from laboratory investigations [Gross, T. S., J. J. Wiebe, V. Centonze, L. Centonze, T. Schoeb, and A. J. Hosmer. Effects of Atrazine Treatments of Freshwater Turtle Eggs: An Evaluation of Endocrine Disruption, Sex Reversal and Developmental Toxicity Effects. Presented at SETAC 20th Annual Meeting, Philadelphia, PA. November 14-18. 1999]. Syngenta stated that the panel "concluded that ...atrazine did not pose a significant threat to aquatic wildlife, however, they also noted a lack of data in certain areas." The report containing the partial presentation of data showed "no effects on sex ratio, development or survival from realistic nest exposures to atrazine." In addition, Syngenta cited Hosmer *et al.* [Effects of Atrazine on the Sex Ratio of *Daphnia pulex*; Study No. 45810; (919) (1201-99, 400233)] as a study where the findings of Dodson *et al.* 1999 could not be replicated.

Agency Response

The Agency agrees that the study of the effects of xenobiotics on endocrine disruption in wildlife is a relatively new area of investigation. A statement to that effect will precede the original statements. The Agency looks forward to the opportunity to review the referenced studies. Changes in these statements will be considered after such review.

Fetal resorptions (page 3)

Syngenta claims that the mammalian studies cited in Appendix XI do not support the statement about fetal resorptions since the duration of treatment in these studies was 11 days and dose

concentrations are much greater than could be found in the environment.

Agency Response

Laboratory studies with rabbits show fetal resorptions at 2,475 ppm, which is an unlikely residue level for wildlife exposure. The statement was deleted.

Incident reports (pages 4, 21)

The full report of these is being provided with this response. As Syngenta also requested, EPA has reconciled the different numbers of incidents reported and has provided in the RED the time period over which the incidents were collected, 1991 through 1999.

Crop Use and Usage (pages 5-8)

Mitigation measures

EPA acknowledges the measures taken by Syngenta in recent years to lower application rates and to reduce environmental exposure. However, based on the 1998 survey data provided by Syngenta, there are still corn and sorghum acres with use rates that exceed the 1992 label rate. (See next comment)

Maximum and Typical Rates

The rate of 2.0 lbs. a.i./A is the single maximum application rate used for modeling of corn and sorghum scenarios, and the rate 4.0 lbs. a.i./A was used for the sugarcane scenario. However, based on the 1998 use survey for corn and sorghum (Table 1, page 9) provided by Syngenta, the application rate has exceeded the 2 lb. a.i./A rate for about 8% of corn acres and 12 % of sorghum acres. Comparing this with the annual limit of 2.5 lb. a.i./A rate, there are about 5% of acres for both corn and sorghum that have violated the label limit, which was changed since 1992.

QUA Report

EPA has provided to Syngenta the 1999 QUA report for further discussion.

Atrazine Fate Characterization (pages 10 to 12)

Laboratory Data

Syngenta claimed the half-life values for aerobic soil metabolism ranged from 20 to 146 days with a mean of 44 ± 38.6 days. The registrant needs to submit all the referenced study reports for EFED review and also submit the anaerobic aquatic metabolism study reports.

Field Dissipation

Syngenta should submit any new studies not yet reviewed by EFED. Also the use of nonlinear first-order regression equations has not been adopted yet by EFED.

Page 3 (2nd paragraph) and Pages 11, 12 (Field Dissipation)

Use of “true” half-life of atrazine under field conditions in the revised assessment.

In addition to the biological and chemical reactions, such as soil aerobic and anaerobic degradation, volatilization, etc, the field dissipation of atrazine also took physical movements into consideration, such as leaching and runoff, where atrazine moves with the water. For this reason, field dissipation rate and biological degradation rate are not identical. Since the water movement has been accounted for in the PRZM modeling, the use of the field dissipation rate will be double-counting the degradation. For this reason, the laboratory results (such as soil aerobic and anaerobic metabolism rates) were used (and should be used) in the assessment.

The modeling approach was used to provide the aquatic exposure estimate to a small farm pond, whereas for other types of aquatic environments, the monitoring results were used for exposure. Therefore, the discussion of the field dissipation results is irrelevant to those assessments.

Atrazine Exposure Characterization (pages 12, 13)

Monitoring Data

EFED states that the NAWQA monitoring results are likely to underestimate some environmental concentrations, due to the fact that NAWQA sampling is not targeted at the high atrazine use areas.

Exposure Modeling (pages 13 to 15)

Although the farm pond modeling approach was used with atrazine, the overall conclusions of the risk assessment relied principally on monitoring data, not on modeling. EFED has refined the assessment well beyond the modeling scenarios so that the major emphasis of the conclusions derives from the ample monitoring data available for the chemical. Therefore, any changes to the modeling scenarios used will have little, if any, effect on the overall risk assessment.

a) sugarcane scenario

The application rate of 4.0 lb ai/A and aerial application are supported in the label. Even assuming no aerial application is allowed, the exposure estimates will not change much. As described in page V-4, for the sugarcane scenario, more than 99% of the EEC contribution is from runoff.

Doane Marketing Research data were quoted by the registrant, but since no details were provided, EFED will not use these data.

b) use of 20-year historical weather data

Only 20-year data are available. Based on the Weibull plot, the upper 10th percentile can be established.

c) Syngenta's regression equation for estimating Koc

The proposed regression has not been critically reviewed by EFED. The current EFED policy is to regress Kd with OC to estimate Koc.

d) a single metabolism half-life should not be used

EFED has used the higher value of the two half-life values (146 and 140 days) for a conservative estimation.

e) Syngenta requests the detailed PRZM input files

The weather files are standard in the PRZM (PIRANHA PACKAGE) (EPA/600/C-92/002). The PRZM input file will be made available.

f) Other PRZM input parameters

The values of Henry's Law constant and vapor pressure are correct. The supporting document for new values of KBACW and KBACS needs to be reviewed by EFED. Even if the suggested values are used, the results are not expected to change much.

g) Considering outflow in EXAMS

The standard pond scenario assumes the runoff input is balanced by the transpiration from the pond surface, and thus a steady state flow condition exists. This PRZM/EXAMS approach has been implemented in EFED for some time. It is the standard approach in EFED for aquatic exposure approach.

possible underestimation of potential local high concentration at the edge

EFED believes that it is possible that underestimation may occur due to imperfect mixing.

use rate

EFED used the maximum allowed application rate according to the label. Although the typical rate can be lower, it is policy for conservative estimates that the maximum rate is assessed.

Effects Characterization (page 15)

Kettle, et. al.: Syngenta claims that the authors have discounted the results of their work in

subsequent publications.

Agency Response

Please provide references for subsequent publications by these authors. In personal communication with EFED (1/23/01), Dr. Kettle indicated that he is unaware of any further publications in which he or his team discounted their earlier results.

Moore and Waring: Syngenta challenges several aspects of this study; EFED generally concurs and has acknowledged the study limitations.

Agency Response

Because of accuracy concerns with the measured values in this study EFED chose to refer to the nominal lowest concentration of 0.5ug/L, rather than the 10-fold lower measured value of 0.045 ug/L, for discussing effects. EFED agrees with Syngenta that atrazine is not lipophilic, but this does not appear to be relevant to the results. All in all, because of the many uncertainties associated with this study EFED agrees that further research is necessary, particularly in the areas of sublethal effects and behavior.

Endocrine modulation (page 17)

See Agency comment above re: endocrine disruption. References to endocrine disruption have been deleted for now, however.

Terrestrial Risk Assessment (pages 17-18)

Mammalian toxicity

Syngenta comments that for small mammal toxicity EPA notes LOAEL and NOAEL values of 50 and 10 ppm, respectively, from reductions in pup body weight, however, the correct LOAEL is 500 ppm and the correct NOAEL is 50 ppm (MRID No. 40431303).

Agency Response

Both values are in fact NOAELs for parent and first generation effects. The values are correct, and EFED has clarified the text to refer to the respective effects clearly.

Avian chronic toxicity

Syngenta comments: "The RED Chapter states an LOAEL and NOAEL for bobwhite quail and mallard of 225 and 75 ppm, respectively, however the correct LOAEL is 675 ppm and the correct NOAEL is 225 ppm."

Agency Response

EFED agrees and has corrected the draft references.

Foliar Half-Life (page 18)

EFED believes that Syngenta has made an error in their submission. The value for Florida turf after irrigation was confirmed to be 6 days. EFED agrees to delete the statement about irrigation increasing the half-life, however. As stated earlier, results from the first study are for dislodgeable residues only. Those from the second and third studies are for turf, only. If the Terrestrial Fate Model is used, the default value is 35 days if no data are available.

Water Assessment (pages 22 to 27)

Page 22:

Refers to Atrazine concerns - bullet 1.

Agency Response

Despite Syngenta's claims, it is true that "Atrazine is mobile, is found in runoff to surface waters and is present in ground water."

Refers to bullet 4, atrazine in rainfall.

Agency Response

The detections of atrazine in rainfall raise potential concerns for ecological risk. Although the limited rainfall monitoring shows low concentrations, potential risk from this source of exposure cannot be excluded.

Page 23:

Syngenta refers to page 21, Exposure characterization (lakes and reservoir).

Agency Response

As stated in the draft RED, the atrazine concentration may reach up to 88.4 ug/L in surface water from drinking water reservoirs (Baier et al., 1985), and up to 69.4 ug/L (Waldron, 1974). The intention of the statement is to show the high detections; the statement is correct.

Page 24:

Syngenta raised the issue of EFED's presentation of the distributions of maximum concentration values across sampling sites for data from the 1992-3 USGS study, from reservoirs/lakes and streams, and from the Chesapeake Bay and Louisiana bayous.

Agency Response

EFED has reported maximum concentrations in the figures from all these studies based on the monitoring results available. There are some uncertainties in these maximum values, since all of the sampling was not done continuously on a daily basis. If sampling missed a runoff event (i.e., a rainfall event), then the peak value would also have been missed. The registrant has raised the issue of different exposure periods. Since all of these monitoring studies were designed specifically for the purpose of assessing the water-quality conditions of these sites, they were thus not optimized for assessing occurrence and levels of atrazine. However, without an abundance of robust monitoring data available for our exposure purposes, EFED made conservative estimates using the "available" maximum concentrations for screening purposes. The registrant is encouraged to submit any robust ecological monitoring results available for the purpose of further refining the assessment.

Syngenta refers to pages 46-50, Drinking Water Assessment - comments on HED RED.

Agency Response

EFED's new DW memo has addressed these comments.

Syngenta refers to pages 21-22, ARP database:

Agency Response

Syngenta emphasized the percent (%) of samples exceeding 20 ug/L, whereas EFED identified the CWSs.

Pages 25- 27:

Rural Well Survey: Syngenta claims point source contamination for wells > the MCL.

Agency Response

Syngenta should provide their follow-up report to show the results of the point source contamination. As stated in the EFED DW memo, since only one sample was collected for one well, the uncertainty in reporting the maximum concentration can be great. This single sample issue also complicates the DAR (deethylatrazine to atrazine ratios) interpretation. It is also impossible to tell the time period between the sampling time and the atrazine application time with a single well sample. The conversion of atrazine to deethylatrazine is a continuous process. Depending on the spot in the transformation curve, the DAR can vary significantly.

Data Requirements (page 28)

Aquatic photodegradation: EFED is not aware of this study. Please resubmit through normal channels.

Spray Drift: Agreed--Requirements may be fulfilled by Syngenta's membership in the Spray Drift Task Force. EFED has changed the notation in the Data Requirements Table.

Aquatic sediment: Agreed--no data required. Appendix XIV has been corrected.

Specific Comments/Corrections Suggested (page 31)

List of tables and figures: agree. This will be provided. In the meantime, all Appendix titles/numbering have been checked and corrected.

Reference to Figure 2-1: Has been deleted and the figure is clearly referred to and described on the page on which it appears.

Synergism references are cited in the Appendix on Effects.

EFED has changed/added references to "second largest poundage," "coated fertilizer granule," and "maximum single application rate."

Mechanism of action: EFED believes that its statement of mechanism of action is correct and is not aware of data indicating reversibility of photosynthesis. Even if such data are available, EFED does not believe they are relevant.

Mammalian chronic toxicity: See comments above.

Page 32

Avian chronic toxicity: Agreed--see comments above.

"Percent loading to pond..." The text has been modified to identify source/type of data.

"Cotton use..." EFED is rechecking the original report for this incident.

Numbers of incident reports have been checked/reconciled.

Aerobic Soil references have been reconciled in Appendix II. EFED does not agree with the half-life value proposed by Syngenta, however.

Detection of degradates (as stated on p.44) has been corrected.

The incomplete sentence on page 62 has been completed. However, EFED does not agree with Syngenta's discussion of the dissipation half-life.

Typical sugarcane use rate has been changed to 2.6 lbs. a.i./A per BEAD.

Page 34

Corn Loss Incidents: Syngenta claims that “It is highly unlikely that atrazine is the causative agent of corn yield loss” with its “excellent selectivity to corn, even at excessive rates...Syngenta Technical Service Department records can show there are no complaints that atrazine causes corn injury.”

Agency Response

EFED has checked the original records and found 14 reports sent by Novartis (Syngenta) where corn yield loss resulted from atrazine use .

Appendix XI, p.6, paragraph 2: Contains no errors, but the text on LD50 values has been modified to provide better clarity.

Appendix XI p.6-7: Units for doses have been corrected, as noted above.

“Tidal pond” has been changed to the more familiar term, “tidal pool”.

Toxicity values: The toxicity value for rainbow trout was recalculated and determined to be 5.3 ppm, not 4.5 ppm as reported by the laboratory. The value for estuarine fish has been corrected. There was no error for estuarine invertebrates.

Page 35

Rainbow trout value has been corrected as noted on both pages 35 and 36.

Acute EC50 for Algae

Syngenta comment

“The reported acute EC50 value of 1 ug/L for algae by Torres and O’Flaherty (1976) is not an EC50 but rather a concentration that significantly decreased chlorophyll production after 7 days of exposure for three algal species (not five)...A value of 33 ug/L based on numerous plant species is therefore more scientifically valid than an extremely low value of 1 ug/L reported from one study.”

Agency Response

Although EC50 values typically refer to growth, cell counts, or density, an EC50 value can be provided for any endpoint specified by the author. It is still EFED policy to use the endpoint from the most sensitive species in first/second tier assessments. EFED agrees that results from a higher tier assessment may be different.

Duckweed and *Isochrysis galbana* toxicity: EFED does not average toxicity values from several studies on the same species. It is EFED policy to use the lowest value for first/second tier

ecological assessments.

The Cohn study (1985) does reference the growing season (months) where it is mentioned in the text/tables.

Page 36

“Gruessner”—corrected.

Pond risk characterization

Syngenta comment

The draft RED uses wording that suggests that concentrations exceeded thresholds for entire years (“All years... exceed levels...”, etc). In fact the result only supports the statement that threshold concentrations were potentially exceeded at some time during the year, for as short a period of time as one instantaneous measurement.

Agency Response

Agreed. The text has been modified accordingly.

Davies reference: Concentration values have been included in the text.

Unpublished reference on p.25: Data were referenced in the text. A published report will be made available.

Page 37

Product Chemistry and Major Degradates: Agreed. Minor errors have been corrected in Appendix I.

Page 38

Aerobic and anaerobic soil study references were clarified in Appendix II.

Appendices to Comments

General conclusions and specific comments from Syngenta’s consultants will be considered during the Public Comment Phase.